

# Morgan Lewis

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**VIA CM/ECF**

Honorable Jennifer L. Hall  
J. Caleb Boggs Federal Building  
844 N. King Street, Room 6312  
Wilmington, DE 19801-3555

Re: Nippon Shinyaku Co. v. Sarepta Therapeutics, Inc., C.A. No. 21-1015-JLH

Dear Judge Hall:



I write on behalf of Nippon Shinyaku Co., Ltd. and NS Pharma, Inc. (collectively, “NS”) and Sarepta Therapeutics, Inc. and the University of Western Australia (collectively, “Sarepta”)—the parties to the above-referenced action—regarding pre-trial scheduling leading up to the December 6, 2024 trial. The parties have agreed upon the interim dates contained in the stipulation attached hereto as Exhibit A. However, the parties have disputes regarding two issues pertaining to pre-trial scheduling that we wish to bring to the Court’s attention for resolution:

***Issue 1 – Scope of NS’s Expert Dr. Matthew J.A. Wood’s Reports/Testimony***

Sarepta’s Position: During discussions regarding the scheduling stipulation, NS revealed that it intended for Dr. Matthew Wood (“Dr. Wood”) to provide a supplemental expert report. Dr. Wood, however, remains bound by his sworn promise not to opine on invalidity of the Wilton Patents, which should be the only topic of any further expert discovery. D.I. 326 ¶ 3 (“I will not be offering opinions concerning the infringement or validity of U.S. Patent Nos. 9,994,851, 10,227,590 or 10,266,827, which I understand are the patents being asserted by Sarepta and UWA.”); *see also id.* ¶ 15 (declaring “under penalty of perjury under the laws of the United States that the foregoing is true and correct”). In the same sworn declaration, Dr. Wood stated he would opine on “the state of the art of exon skipping therapies for DMD and the validity of NS’s patents.” *Id.* ¶ 14. To overcome Sarepta’s objections to Dr. Wood, NS relied on Dr. Wood’s promises, arguing that “Dr. Wood is capable of serving as an expert in this matter without divulging or using any confidential or privileged information he may have received from Sarepta . . . because such information will

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Honorable Jennifer L. Hall  
Page 2

not be implicated by his work in this litigation.” D.I. 325 at 1. Ultimately, the Court agreed with NS and declined to disqualify Dr. Wood because it was “unpersuaded on this record that Dr. Wood received the type of information in those engagements that would require his disqualification in this litigation,” particularly where “discovery is now complete.” D.I. 543; *see also* D.I. 553 (declining to exclude certain testimony as not opinions on state of mind). NS cannot now back away from its own arguments and Dr. Wood’s promises, which are part of the record and case stage that the Court relied on in deciding in NS’s favor. Here, per the Court’s instructions and the Parties’ agreement, the Supplemental Technical Expert reports are only “related to issues for which Nippon Shinyaku bears the burden of proof that are implicated by the Court’s clarified and/or amended claim construction.” Stipulation and [Proposed] Amended Scheduling Order (concurrently filed). Neither of the two issues Dr. Wood swore would be the subject of his testimony—“the state of the art of exon skipping therapies for DMD and the validity of NS’s patents”—are issues for which NS bears the burden of proof or are implicated by the Court’s clarified and/or amended claim construction, which only affects the Wilton Patent. Dr. Wood should not now be allowed to break his sworn promises, which formed the basis for the Court’s allowance of his testimony, and testify regarding invalidity of the Wilton Patent.

NS’s Position: Sarepta purports to transform a routine scheduling submission into a fourth bite at the apple seeking to once again exclude and/or limit portions of Dr. Wood’s anticipated opinions and testimony. Sarepta has no basis for including its arguments with respect to Dr. Wood’s testimony as part of this Court’s amended scheduling order. It is simply not relevant to the Court’s consideration of this largely agreed scheduling order. Further, Sarepta previously raised this same argument in motions pertaining to Dr. Wood (*see* D.I. 385; D.I. 395 at 14) and the Court previously rejected this argument in denying those motions. D.I. 543, 553. The Court’s denial was in no way premised on Dr. Wood’s then-applicable statement (made nearly a full year ago) that he would not offer opinions regarding infringement and/or invalidity of the then-asserted Sarepta Patents. *Id.* Dr. Wood’s supplemental opinions are consistent in scope with those he previously offered, and this Court allowed. As one of NS’s responses to Sarepta’s motions noted, consistent with his declaration, Dr. Wood offered opinions as to what a POSA would understand the inventors had invented upon reviewing the specification of the Sarepta Patents. D.I. 387 at 2. These opinions, as well as additional information relating to the state of the art of exon skipping therapies for DMD, are implicated by the Court’s clarified and amended claim construction. Sarepta’s belated effort to re-raise the identical issue should be rejected. There was no reason to unfairly prejudice NS in its choice of expert and to limit Dr. Wood’s opinions before, much less now, after the Court considered and rejected the same argument in denying Sarepta’s multiple attempts to disqualify or strike Dr. Wood’s opinions.

***Issue 2 – Whether the Court Will Entertain Supplemental Summary Judgment Motions Based on New Expert Opinions and Revised Claim Construction***

NS’s Position: As the Court is aware, the new claim construction ruling drastically altered the case landscape. *See, e.g.*, D.I. 570, Pretrial Conference Tr., at 80:18-25 (Court noting that it “understand[s] plaintiffs’ point that they would have emphasized different things in

Honorable Jennifer L. Hall  
Page 3

the expert report [had NS had the Court's revised claim construction]. And I appreciate that."); *see also id.* at 73:2-15, 73: 21-74:2 (discussing how NS would still have a Section 112 defense—albeit a different scope one—in light of Court's revised claim construction). Had NS had the Court's revised claim construction at the time of its previous expert reports and summary judgment filings, it would have had different grounds on which to move for summary judgment. To preclude NS from having an opportunity to now raise case dispositive issues based on new expert opinions in light of the Court's revised claim construction would be unduly prejudicial. Permitting limited supplemental summary judgment briefing may help streamline issues for trial and obviate the need for a large portion of the case.

NS is cognizant of the fact that the Court has already expended significant resources into resolving previously filed summary judgment and *Daubert* motions in advance of the previously-scheduled May 2024 trial. Therefore, NS does not seek any additional pages for summary judgment briefing on top of the page limits the parties have agreed to for *Daubert* motions (limited to 20 pages for the opening briefs, 20 pages for answering briefs, and 10 pages for reply briefs, per side) as reflected in Exhibit A hereto.

Sarepta's Position: There is neither cause nor time for a second complete round of summary judgment briefing, which, to be clear, is NS's request despite its proposed "Supplemental" moniker. NS does not seek to merely "supplement" existing motions for summary judgment that are implicated by the Court's clarified and/or amended claim construction to address that construction. Rather, it wants to raise unidentified "different grounds on which to move for summary judgment." This is not "limited supplemental summary judgment briefing" as NS claims. It is full blown summary judgment practice, with its attendant heavy burdens on the Court and the Parties—some of which NS's proposal does not even try to account for, such as the separate concise statements of facts and responses thereto required for dispositive motions under the existing Scheduling Order (D.I. 143 ¶ 13(b)). Those burdens will be particularly onerous on the Court here, where NS's proposal would leave the Court only a few weeks (spanning Thanksgiving) to resolve such summary judgment motions once briefing is complete before jury selection on December 13, 2024. Burdening the Court and Parties in such a way is uncalled for, particularly where the Court contemplated only limited supplemental expert discovery addressing the clarified and/or revised claim construction because "[i]t looked to [the Court] from the expert reports like there was a 112 defense still in" NS's expert reports. D.I. 570, Pretrial Conference Tr. 80:21-22; *see also id.* at 70:17-21 (NS's counsel stating that if the Court "adopts or the clarification [the Court] adopt[s]" is that the antisense oligonucleotides "ha[ve] to be 100% complementary or highly complementary ... then the experts have opined on it and our expert has an opinion"); 71:20-24 (NS's counsel agreeing with the Court that there is "a path forward" to "fix this without digging a bigger hole or restarting all the expert reports").

Separately, there is no prejudice to NS by denying it a second, unplanned bite at the summary judgment apple. Indeed, NS does not specify how it might be prejudiced by such a denial. As the Court is aware, the parties hotly contest various factual issues relating to NS's 112 defenses and has already denied NS's summary judgment on these grounds based on there

Honorable Jennifer L. Hall  
Page 4

being genuine disputes of material fact. D.I. 549. NS does not even try to explain how any new material in the limited Supplemental Technical Expert Reports will resolve those genuine, material factual disputes. If anything, NS's assertion that it needed additional expert discovery suggests there will remain genuine disputes of material fact in need of resolution at trial. NS's request for a second round of summary judgment briefing should be denied.

Counsel are available should the Court have any questions.

Respectfully submitted,

*/s/ Amy M. Dudash*

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CC: Counsel of Record (Via CM/ECF)